

IX. 510(k) Summary

JUL 26 2000

K001340

SUBMITTER: DePuy AcroMed, Inc.  
325 Paramount Drive  
Raynham, MA 02780

CONTACT PERSON: Karen F. Jurczak

DATE PREPARED: April 27, 2000

CLASSIFICATION NAME: Implant, fixation device  
Spinal Intervertebral Body Fixation Orthosis Device

PROPRIETARY NAME: Stackable Cage™ System

PREDICATE DEVICES: Stackable Cage™ System – K990148

INTENDED USE: The Stackable Cage System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The Stackable Cage System is also indicated for treating fractures of the thoracic and lumbar spine.

The Stackable Cage System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

The Stackable Cage System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the Stackable Cage System include DePuy AcroMed titanium plate or rod systems (e.g., Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss Miami, TiMX, Profile).

MATERIALS: Carbon-fiber reinforced polymer and titanium alloy

PERFORMANCE DATA: Mechanical, Chemical and Biomechanical Testing were presented.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

**JUL 26 2000**

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Frank Maas  
Regulatory Affairs Manager  
DePuy AcroMed  
325 Paramount Drive  
Raynham, Massachusetts 02767-0350

Re: K001340  
Trade Name: Stackable Cage™ System  
Regulatory Class: II  
Product Code: MQP  
Dated: April 26, 2000  
Received: April 27, 2000

Dear Mr. Maas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

*Danner R. Vochner*

*GA*

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**IV. Indications for Use**

510(k) Number (if known): K001340

Device Name: Stackable Cage™ System

The Stackable Cage System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

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(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter

Use: \_\_\_\_\_  
(Per 21 CFR 801.109)

Dan R. Lockner  
(Division Sign-Off)

DePuy AcroMed, Inc.

Division of General Restorative Devices  
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